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L7: Entry 58 of 66

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TITLE: Product and process for transferring passive immunity to newborn domestic animals using ultrafiltered whey containing immunoglobulins

BSPR:

As is common with most domestic animals, bovine calves are born without immunity. Passive immunity is transferred on a postpartum basis from a dam (mother) to the newborn calf through an initial mammary gland secretion known as colostrum. As illustrated by FIG. 1, this initial colostrum secretion contains rapidly diminishing levels of immunologically active, large molecular weight proteins known as immunoglobulins (abbreviated below as "Ig"). These Ig molecules possess antibody properties, are actively produced by mature animals, and enhance immunity to infection by bacteria, viruses or parasites. At birth, a calf lacks Ig in its blood serum. Only as a direct response to ingestion and absorption of a quantity and quality of Ig from maternal colostrum shortly after birth can a calf's immune system function efficiently.

BSPR:

To combat the immunity deficiency problems outlined above, some dairymen having small dairy herds manually milk what they believe to be an adequate quantity of colostrum from a dam and force feed it to its newborn calf during the critical absorption period. This labor intensive method of controlling the timing and quantity of colostrum consumption cannot compensate for colostrum having a low Ig concentration or an inadequate spectrum of pathogen specific antibodies. Since only complex, time consuming laboratory tests can measure the colostrum Ig concentration and antibody distribution, these dairymen have no way of verifying that the colostrum which they laboriously obtain and force feed to newborn calves will provide adequate levels of passive immunity.

DRPR:

FIG. 2 is a graph illustrating the bovine gut closure phenomenon where the ability of the gut to absorb large Ig molecules rapidly diminishes after birth. This graph is presented for illustrative purposes only and is not drawn to scale.

DEPR:

A preferred test, known as the "EIA" test, is capable of measuring the distribution and concentration of pathogen specific antibodies in the filtered product and is described in an article

entitled "Quantification of Bovine IgG, IgM and IgA Antibodies To Clostridium Perfringens B-Toxin By Enzyme Immunoassay I. Preparturient Immunization For Enhancement Of Passive Transfer of Immunity." This article was published in Veterinary Immunology and Immunopathology, Vol. 4 (1983) at pp. 579-591 and was authored by W. A. Fleenor and G. H. Stott. The disclosure of that article is hereby incorporated by reference. The EIA test procedure discussed in that article is known to persons of ordinary skill in the appropriate field.

DEPR:

The passive immunity transfer mechanism implemented according to the present invention has been discussed primarily in connection with dairy cattle. However, beef cattle and other non-bovine domestic animals that achieve passive immunity to disease in response to ingestion of a colostrum-like mammary gland secretion can also benefit from implementation of the process of the present invention. Dairy cattle have been focussed upon primarily due to the recognized and publicized immunity problems encountered and the resulting highly adverse economic impact on dairymen.

DEPR:

A recently published research study suggests the possibility that bovine antibodies such as the anti-rotavirus antibody may possess sufficient activity against human rotavirus strains to provide protection against symptomatic infection. If further investigation establishes that bovine antibodies do in fact combat selected human diseases, the immunologically active filtered product of the present invention could be used to provide protection against those diseases.

DEPR:

If the experimental results are evaluated as indicating that a minimum of twenty-five grams or an optimum level of forty to fifty grams of whey-derived Ig should be administered to a calf having a weight of one hundred pounds, these results indicate that at least a minimum 0.055 and preferably 0.09-0.10 percent ratio of whey-derived Ig to animal weight should be administered to any neonate calf. Applying this ratio to a neonate calf having a body weight of one hundred and twenty-five pounds (56,750 grams) indicates that a minimum of appropriately thirty-one grams of whey-derived Ig should be administered to that calf in a single dose given within four hours postpartum. Various other product dosage levels, dosage distributions and dosage combinations with natural colostrum would be readily apparent to one of ordinary skill in the art in view of the detailed experimental results tabulated above. In addition, it is clear that the whey-derived product could readily function as a supplement for natural colostrum to either boost the effective level of Ig in natural colostrum having an insufficient level of Ig or to serve as a source of broad spectrum active immunity ultimately achieved by the immune system of a calf or other bovine. The whey-derived product could also be used on a continuous basis as a food supplement for a calf, a mature cow or any other animal to enable the immunologically active immunoglobulin molecules in the product to attack pathogens

present in the digestive system of the animal. Comparatively low levels of the product could be used when it functions as a food supplement, potentially on the order of approximately two grams or less per day per hundred pounds of animal weight.

DEPV:

7. Infectious Bovine Rhinotracheitis; and

ORPL:

Physiological Effects of the Colostral Peptide, Colostrokinin, and Inanition on Immunoglobulin Absorption and Adrenal/Thyroid Response in the Bovine Neonate, T. G. Schlagheck, A Dissertation Submitted in Partial Fulfillment of the Requirements for the Degree of Doctor of Philosophy in the Graduate College of the University of Arizona (1983).

ORPL:

Characterization of Monoclonal Antibodies to Bovine IgG1, W. A. Fleenor, D. O. Lucas, G. H. Stott and A. J. Guidry, Veterinary Immunology and Immunopathology, 6(1984) 365-378 Elsevier Science Publishers B. V., Amsterdam--Printed in the Netherlands.

ORPL:

Quantification of Bovine IgG, IgM and IgA Antibodies to Clostridium Perfringens B-Toxin by Enzyme Immunoassay I. Preparturient Immunization for Enhancement of Passive Transfer of Immunity, W. A. Fleenor and G. H. Stott, Dept. of Animal Science, U. of A., Veterinary Immunology and Immunopathology, 4 (1983) 579-591, Elsevier Science Publishers B. V., Amsterdam--Printed in the Netherlands.

ORPL:

Preparation of Bovine Immunoglobulins and Free Secretory Component and Their Specific Antisera, J. E. Butler and C. F. Maxwell, J. Dairy Sci 55: 151.